EXHIBIT 1

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL No. 1456
	CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	Judge Patti B. Saris
	Chief Magistrate Judge Marianne B. Bowler
	[FILED UNDER SEAL PURSUANT TO COURT ORDER]

DECLARATION OF RAYMOND S. HARTMAN
IN SUPPORT OF PLAINTIFFS' CLAIMS OF LIABILITY
AND CALCUATION OF DAMAGES

Since it is necessary for a manufacturer to increase the spread of the relevant physician-administered drug above what would have been the case absent the fraud in order to implement and benefit from the AWP scheme, I find causation and liability for any NDC of any of these drugs if Equation (1a) of my September 3, 2004 Declaration is found to hold. Specifically the alleged AWP scheme excessively raised reimbursement rates for drug j of Defendant k if

(1a) $Spread_{jk} > Spread_{jk}^{but\text{-}for}$.

C. Yardsticks for a Finding of Causation and Liability

57. Equation (1a) explicitly relies upon the notion of the yardsticks that I discussed in my earlier Declarations and that the Court has recognized at p. 63 of the *Memorandum and Order*.

58. As noted above, the alleged AWP scheme was effectuated when a manufacturer increased the AWP of the drug and/or decreased its ASP in order to offer financial incentives to providers to move market share. Reliance upon increased, non-transparent and unmonitored spreads became strategically useful to drug manufacturers when they faced increased therapeutic competition. In the absence of therapeutic competition, a given manufacturer would find it unnecessary **and unprofitable (if ASP were reduced)** to increase spreads to move market share. Hence, as noted with my discussion of Table 3 above, successful "break-through" innovator drugs serve as reasonable yardsticks for "but-for" spreads, specifically, for spreads that would be anticipated in the market when spread manipulation was unnecessary to move market share and was therefore not undertaken.

59. While I have requested of Defendants data for as many drugs in Tables 3.A and 3.B as possible, I have received limited usable data. I have, however, been able to make use of some Defendant data, data and analyses of Defendants' experts, and other data. I will continue to examine data I have requested of Counsel and will refine my yardsticks as such data are made available.

a) Specific physician-administered drugs

- In Attachment H.1, I present AWP and ASP information for Zofran (see Table 3.B). The data for Zofran NDC 00173044200 are compelling. Zofran launched as the first Serotonin 5-HT3 Blocker (antiemetic), a unique market niche. It did not face therapeutic competition until Kytril launched in 1994. Once Kytril did launch, the manufacturers of each drug clearly used spread (see Attachment F of this Declaration) to compete for market share, as alleged and as described in Attachment E of my September 3, 2004 Declaration. Prior to the time that GSK felt compelled to increase spread to move market share in 1994, its spread was 18.6%-20% for the three years, 1991-1993. Once therapeutic competition arose, the spreads were increased to compete for market share, as described in Attachment F to this Declaration.[59]
- In Attachment H.2, I present the AWPs and ASPs for Taxol from its launch in 1993. At that time, it was the only therapeutic competitor offering Paclitaxel. When it launched, using RedBook AWPs, its spread was 25% and remained at 25-27% from 1994 until 2000, when generic launch introduced price competition to move market share. When it launched, using First DataBank AWPs, its spread was 20% and remained at 21-22% from 1994 until 2000, when generic launch introduced price competition to move market share.
- In Attachment H.3, I present the AWPs and ASPs of Blenoxane, which was not included in Table 3.B. Using Red Book AWPs, it launched in 1993 with a spread of about 27% and remained at that level until it faced competition motivating it to increase its spread. Using First DataBank AWPs, it launched in 1993 with a spread of about 22% and remained at that level until it faced competition motivating it to increase its spread.
- I conclude that the relevant yardsticks provided by innovator single-source physician-administered drugs untainted by the AWP inflation scheme and based upon Red Book AWPs (in this case, Class drugs prior to the time they began to effectuate the AWP scheme) range from 18-27%. If I based my yardsticks upon First DataBank AWPs, the range would be 18%-22%

b) As cited in ¶ 22. b) above, in the course of my analysis for this matter I have reviewed a variety of publicly-available survey research summarizing the "market" expectations of spreads for single-source physician-administered drugs. For this group, the range of reasonably anticipated spreads found in the survey research is 11%-25%, which corroborates the comparator drugs introduced in ¶ 59.a) above.

c) Dr. Gaier admits to a yardstick of 20-25% in his Rebuttal Declaration for all single-source innovator drugs.[60]

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[59] Note that Zofran's AWPs are equivalent in the RedBook and First DataBank. This is not the case for Taxol and Blenoxane.

[60] In the process **Dr. Gaier reveals confusion** regarding the coincidence of the proffered opinions of Dr. Schondelmeyer and me. Specifically, at his ¶ 58 Dr. Gaier states, "Notwithstanding the record evidence that many payors did not expect AWP was a signal for manufacturer's selling price, Dr. Hartman's assertion that payors were harmed because they incorrectly 'expected that AWP is larger than ASP by a

d) Reimbursement patterns for most physician-administered drugs, whether administered under Medicare coverage or under private commercial payor coverage, are driven primarily by Medicare reimbursement practices.[61] As a result, contracts negotiated by commercial payors with provider groups offer less information about "revealed preferences" or "revealed expectations" about spreads than do TPP contracts with PBMs for single-source self-administered orals.[62]

e) Given the information available, I weight most heavily the evidence from the physician-administered comparator drugs and the publicly available survey research for physician-administered drugs. I conclude that a reasonable range of yardsticks for spreads untainted by the AWP scheme is 11%-25%, using First DataBank. However, using RedBook AWPs, I conclude that a reasonable range of yardsticks for spreads untainted by the AWP scheme is 11%-27%. To be conservative, I choose 30% as my yardstick for a finding of liability. Specifically, if a manufacturer either raises its AWP and/or lowers its ASP such that the realized spread exceeds 30% for a given NDC for a given period of time (I choose a year), I conclude that the manufacturer has fraudulently increased the spread on that NDC in that period to move market share.

f) It is appropriate to proceed by NDC and its related AWP. It is clear from discovery materials, fact evidence and my analysis in the Lupron matter that manufacturers decide to artificially increase the spread for a given NDC relative to other NDCs for strategic reasons. Indeed, I understand that there has been documentation of the temptation to shop NDCs for the highest AWP.

The fact evidence certainly indicates that manufacturers strategically increase and decrease the spreads of certain NDCs over time relative to other NDCs, as their marketing strategies and product life cycles evolve. Likewise, providers can reasonably be assumed to be profit-maximizing actors who bill the most they can

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reasonably predictable amount' is contradicted by plaintiffs' expert, Dr. Schondelmeyer (Schondelmeyer Declaration, p. 37; *Emphasis added*), who writes:

> 'For most brand name products that are still covered by patent or exclusivity terms, the price relationship between list prices (AWP and WAC) and actual transaction prices (actual acquisition cost or average selling price) for a given class of trade is *reasonably predictable.* That is, the WAC is equal to, or close to (+ or - *5%)* the actual acquisition cost for the community pharmacy class of trade and the AWP, at present, is typically 20 to 25 percent above the WAC, or alternatively, WAC is 16.67 or 20 percent below AWP. *In such cases, a payment policy using AWP as a benchmark (e.g., usually AWP minus a certain percent) may be relatively accurate.*'"

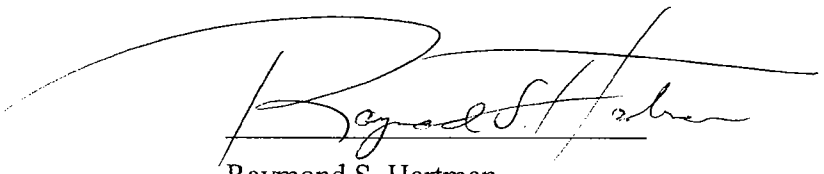
Despite Dr. Gaier's confused assertion to the contrary, there is no contradiction between Dr. Schondelmeyer and me. We are in complete agreement. We both agree that for single-source self-administered innovator drugs, the market **reasonably predicted** that AWP was approximately 20-25% above drug acquisition costs, or the ASP.

[61] Again, See MedPAC Report, chapter 9.

[62] Both Mr. Young and I agree that negotiated reimbursement rates are AWP minus 13%-18% for these drugs (*Memorandum and Order*, p. 64), which allows for the pharmacy margins discussed in Attachment K to this Declaration. For physician-administered drugs, contracted reimbursement rates are AWP ± 15%.

I declare under penalty and perjury that this Declaration is true and correct.

Executed on December 15, 2005



Raymond S. Hartman

Attachment J.4.j: Johnson & Johnson Non-Medicare Damages: Massachusetts (Sub-Class 3) Aggregated by Drug

Nominal Damages

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	Total
Procrit	0	0	1,548	0	1,493	183,009	42,461	248,144	56,525	0	0	72	509,026	509,026	1,551,302
Remicade	0	0	0	0	0	0	0	2,877	36,179	71,044	550,966	622,078	852,014	675,019	2,810,177
Total	0	0	1,548	0	1,493	183,009	42,461	251,020	92,704	71,044	550,966	622,150	1,361,040	1,184,045	4,361,479

Damages Including Pre-Judgment Interest (2005$)

Drug	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003	2004	Total
Procrit	0	0	2,570	0	2,278	267,731	59,547	333,590	72,843	0	0	82	553,933	531,005	1,823,580
Remicade	0	0	0	0	0	0	0	3,867	46,624	87,765	652,468	706,188	927,180	704,166	3,128,259
Total	0	0	2,570	0	2,278	267,731	59,547	337,458	119,467	87,765	652,468	706,270	1,481,113	1,235,171	4,951,838

Attachment G.4.c: Johnson & Johnson Annual Spreads

NDC	Drug	Description	1991	1992	1993	1994	1995	1996	1997	1998	1999	2000	2001	2002	2003
00062740003	Procrit	PROCRIT 4000U/ML AMG	22.5%	22.7%	20.9%										
00062740103	Procrit	PROCRIT 10000U/ML AMG	22.8%	23.2%	23.3%										
00062740201	Procrit	PROCRIT 2000U/ML AMG	24.4%	25.0%	23.6%										
00062740501	Procrit	PROCRIT 3000U/ML AMG	21.2%	25.4%	22.4%										
59676030201	Procrit	PROCRIT 2000 U/ML 6'S			221.3%	24.4%	24.7%	24.2%	23.9%	24.0%	24.0%	20.8%	21.4%	20.5%	18.0%
59676030202	Procrit	PROCRIT 2000 U/ML , INSTITUTIO			20.9%	25.3%	29.6%	30.8%		30.0%	26.3%	20.7%	27.4%	33.6%	66.5%
59676030301	Procrit	PROCRIT 3000 U/ML 6'S				24.2%	25.4%	24.2%	23.7%	23.1%	23.3%	21.2%	21.6%	20.9%	18.5%
59676030302	Procrit	PROCRIT 3000 U/ML 25'S			23.3%	27.0%	28.5%	31.0%		28.4%	25.7%	21.9%	25.2%	30.4%	24.6%
59676030401	Procrit	PROCRIT 4000 U/ML 6'S			51.1%	24.0%	26.0%	24.6%	23.6%	22.7%	22.9%	21.5%	22.3%	22.0%	20.6%
59676030402	Procrit	PROCRIT 4000 U/ML 25'S			26.0%	26.3%	28.4%	30.0%		27.3%	25.9%	19.9%	23.6%	22.7%	22.5%
59676031001	Procrit	PROCRIT 10000 U/ML 6'S			23.5%	23.6%	30.3%	27.3%	27.2%	24.4%	24.6%	22.1%	22.4%	22.0%	22.0%
59676031002	Procrit	PROCRIT 10000 U/ML 25'S			24.9%	23.7%	26.1%	27.2%		30.5%	31.1%	27.0%	29.1%	27.4%	26.9%
59676031201	Procrit	PROCRIT 10,000 U/ML , MULTIDOS					26.0%	47.0%	33.1%	28.2%	27.3%	22.8%	25.1%	24.4%	25.7%
59676032001	Procrit	PROCRIT 20,000 U/ML - 1ML							30.8%	37.7%	31.6%	28.6%	29.9%	28.5%	30.0%
59676034001	Procrit	PROCRIT 40000 U/ML 4'S									25.2%	26.7%	29.1%	27.7%	34.5%
57894003001	Remicade	C168J REMICADE 1PCK US PD								30.8%	33.4%	31.9%	36.1%	33.9%	34.3%

EXHIBIT 2

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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In re: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL DOCKET NO. CIVIL ACTION 01CV12257-PBS

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THIS DOCUMENT RELATES TO:

ALL ACTIONS

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May 5, 2006

9:36 a.m.

Deposition of JAYSON S. DUKES taken by the Plaintiffs, at the offices of Patterson, Belknap, Webb & Tyler, LLP, 1133 Avenue of the Americas, New York, New York, before David Levy, CSR, a Notary Public of the State of New York.

A. CPE.

Q. CPE. CLE for lawyers. And you don't have a background in economics, right?

A. No.

Q. Now, so I understand, are you giving an opinion on whether or not Dr. Hartman's methodology is right or wrong?

A. No.

Q. You tell me. What is your opinion on?

A. My opinion is on taking the methodology as laid out by Dr. Hartman and calculating ASPs and associated spreads based upon that methodology.

Q. So you're using Dr. Hartman's methodology completely without any changes?

A. Yes.

Q. And you're using essentially some other data or some more refined data, at least, to recalculate ASPs, correct?

MR. SCHAU: Object to form.

Q. You can answer that.

A. I'm using the data that was produced

Dr. Hartman did, right? He didn't exclude those discounts.

MR. SCHAU: Object to form.

A. I thought he had.

Q. Okay. Do you have an understanding as to whether or not prompt pay discounts are included or excluded when calculating ASP for the Medicare Modernization Act?

A. I don't.

Q. Same question -- first of all, service fees, what are service fees, as you use it in paragraph 2?

A. Fees for service. Fees for services provided by the specialty distributor.

Q. Do you know what services specifically were provided?

A. No.

Q. Do you know if the fee paid was equal to the service that was actually received?

MR. SCHAU: Object to form.

A. I was not asked to look at that.

Q. Why did you decide to exclude service

fees?

A. Because it was a fee for service, I was told to excluded from the --

Q. Told by whom?

A. Told by counsel.

Q. Did you look at any of the contracts or documents that detail what those services are?

A. I was not asked to.

Q. Okay. So you simply looked for service fees and took them out.

A. Correct.

Q. Okay. And you don't have any rationale for why you did that other than counsel told you to do it.

MR. SCHAU: Object to form.

A. Yeah.

Q. Do you understand that Dr. Hartman kept those service fees in?

A. I don't know that specifically.

Q. Okay. Well, wouldn't you have to know whether or not he kept them in to determine whether or not you were following his methodology?

Q. And you didn't make any attempt to figure out if the fee paid by Centocor for those services actually equaled the value of the services, right?

A. I was not asked to do that.

Q. And do you know if any of those service fees that the specialty distributors paid were ever passed on to any of their customers?

A. I don't know the answer to that.

Q. Okay. Do you know what the Medicare regulations for calculating ASP are in connection with service fees?

A. Not specifically.

Q. But you didn't make any effort in your decision here to follow Medicare's rules.

A. No.

Q. Other than management reports you talked about, do you know what other services Centocor may have been buying here?

A. I don't recall.

Q. And you would have learned that only through some conversation with counsel?

include or exclude them?

A. I do not recall him discussing service fees.

Q. So how did you know whether or not he intended to exclude or include them?

A. Can you repeat the question?

Q. If you don't remember Dr. Hartman discussing service fees, how did you know whether or not he intended to include or exclude them?

A. I spoke with counsel.

Q. Okay. The only reason you took them out is because counsel told you to take them out.

A. Correct.

Q. Okay. Let me go back to your statement of assumptions. Number three, "Patient assistance program fees."

You took them out for Remicade, too; right?

A. Correct.

Q. And why did you take them out?

A. I was told that they were fees for services and they were to be excluded from the

calculation, and the fees -- the transactions were included but the transactions were grossed up to list.

Q. Okay. I'm sorry, I didn't mean to cut you off.

A. I'm done.

Q. Okay. So you took them out because counsel told you to take them out.

A. Correct.

Q. Did you do any investigation at all as to figure out whether or not they were in fact fees for services?

A. I was not asked to look into that.

Q. Do you have any understanding as to whether or not the Medicare ASP calculations require the inclusion or exclusion of these kinds of fees?

A. No.

Q. That would be Exhibit 21.

MR. MACORETTA: That we'll mark as Exhibit Dukes 006.

(Deposition Exhibit Dukes 006,

the invoice was issued, and we compared that price to the list price at that point in time, and we found out that these orders had been placed prior to an effective date taking place.

The customer was -- received that price but the invoice went out after the effective price date. And that's how we did our match-up to, the list price was based upon the price at the date of the invoice.

Q. So the invoice would show a sale below the current list price as of the date of the invoice.

A. Correct.

Q. Okay. Dr. Hartman didn't do this analysis, did he?

MR. SCHAU: Object to form. Foundation.

Q. Do you know if Dr. Hartman performed a similar analysis to identify invoices postdating the order?

A. Not specifically.

Q. By the way, this was only for

Q. You can answer.
A. Can you repeat the question?
Q. Sure. If Centocor did have an agreement with certain customers that it would provide price protection, that would be a reason why the invoice would show the lower price, even though it was dated after the price increase, wouldn't it?
MR. SCHAU: Object to form.
A. That would be a valid assumption.
Q. Okay. Did you do anything to figure out whether or not Centocor had such an arrangement?
A. I was not asked to do so.
Q. And in fact, was it your understanding that that was a way wholesalers make some money, by profiting from this price protection arrangement, buying low and selling a little bit higher?
MR. SCHAU: Object to form.
A. Yes.
Q. Do you know whether or not Dr. Hartman

A. I don't recall that specific conversation.

Q. Your next assumption, you took out, it says you took out units where the sale price was zero for both Procrit and Remicade. I'm looking at assumption 5 on your attachment. That's what you did; right?

A. Yes.

Q. Why did you decide to do that?

A. At the direction of counsel, we were told that these were charity-type donations. Therefore, they should be removed.

Q. Did you do anything to confirm that?

A. No.

Q. I mean, if this was an audit and somebody told you that, you would go ask for some proof that it really was a charity donation; right?

A. It would depend.

Q. Well, you wouldn't just take the company's word that you should take these out, would you?

A. It would depend upon the materiality.

Q. Let's say it was material.

A. Yes.

Q. Yes, you would want some prior verification beyond the company's say-so.

A. Correct.

Q. Okay. Do you know if Dr. Hartman took out the zero price units?

A. He may have.

Q. Well, so you weren't doing this to be consistent with what Dr. Hartman did, then; were you?

A. I was doing this under the direction of counsel.

MR. MACORETTA: Let me hand you what's marked as Exhibit Dukes 008.

(Deposition Exhibit Dukes 008, printout of Exhibit 23 to declaration of Jayson Dukes, marked for identification, as of this date.)

(Document placed before the witness.)

MR. MACORETTA: And let me show you

quantify or clarify that.

Q. Okay. So are you telling me that you interpreted Dr. Hartman's report to be that he took out all the zero unit sales?

A. That's one interpretation.

Q. Is that the interpretation you used? Let me try it this way:

You didn't take out the zero unit sales because you were trying to match what Dr. Hartman did, did you?

A. No.

Q. You did it because the lawyers told you to do it.

A. Correct.

Q. Okay. Your assumption number 7, "Calculating Procrit ASP across all NDCs by year."

And what this means, I take it, is that there are about -- there are how many Procrit NDCs, 7 or 8?

A. Fifteen.

Q. Fifteen, I'm sorry. So you tried to make one ASP for all those NDCs.

Q. Did you ever talk to anybody at either of the companies about using that approach?

A. No.

Q. If I wanted to see the calculations for how you came up with that weighted average, meaning how many sales you used in one period of time vs. how many sales in another period of time, where would those calculations be?

A. Those would be in the spreadsheets that were produced to you all maybe a couple of weeks ago.

Q. There's something that shows that weighted average calculation?

A. There is.

Q. Your assumption number 8, "Remicade managed care analysis."

Why did you decide to do this managed care analysis that we're talking about in assumption number 8?

A. It was within the scope of what I was asked to do by the attorneys.

Q. This isn't something you came up with

on your own, it's something the attorneys told you to do?

A. Yes.

Q. And this is not something Dr. Hartman did, right?

A. I don't believe he did.

Q. Essentially what you're doing here is, you're taking the managed care rebates and subtracting them from AWP in your spread calculation, right?

A. From the amount reimbursed, theoretically reimbursed based upon AWP.

Q. Well, Dr. Hartman assumes that the amount reimbursed is AWP, right?

A. Yes.

Q. And that's what you do with this exception, right?

A. Correct.

Q. Okay. And nowhere does Dr. Hartman have any subtractions from AWP, right?

A. I don't believe so.

Q. Other than counsel telling you to do

Q. Now, is it possible that any of those sales that you looked at or that you took out and moved up to list could have included some of these managed care rebate dollars?

MR. SCHAU: Object to form.

A. No, I'd have to think about that. Right now I don't think I have an opinion on it.

Q. Okay. But as we sit here right now, you're just not sure?

A. I'm not sure. I'd have to think about it.

Q. Do you know what the Medicare ASP calculation rules are on rebates?

A. Not off the top of my head.

Q. I mean, you don't believe that Medicare makes the same calculation you do where you somehow add back in the rebates; right?

MR. SCHAU: Object to form.

A. They do make -- actually, I don't know. I'd be guessing.

Q. Staying on the subject of rebates, if we could go back to paragraph 55, well, let's

declaration, no.

Q. And as part of your work, did you look at all the Procrit customers and decide what class of trade they should be in?

A. No, we were provided a list from the company.

Q. Okay. And at some point, did you do any analysis and move customers from one class of trade to another?

A. No.

Q. Did you resolve any conflicts with customers appearing in more than one class of trade?

A. Yes.

Q. So the classes of trade you used to do your analysis are the same classes of trade that existed at the company previously.

A. Correct.

Q. Is there something that gives us a definition or an explanation of who is in what category and why?

A. Not within the -- actually --

Did you do anything to confirm that in fact, all those chargebacks were to government or managed care?

A. Relied upon the representation of the company.

Q. And you don't know how the company figured out which customer was which for that, right? They just gave you the end product for that?

A. Correct.

Q. Do you know who at Centocor was involved in that process?

A. No, because I wasn't involved in that process. One of my staff was.

Q. So if we wanted to -- I mean, I understand Exhibits 1 or 2 would show us which customers you took out. But to understand, to recreate the methodology as to how that was done, what could tell us that? Have to be a person at the company?

A. To understand their methodology?

Q. Yes, to recreate.

A. Yes.

Q. Okay. Now, who decided that -- I'll take the first one, San Francisco General Hospital, should go from Paraguard Physicians to teaching hospital, was that somebody at FTI or somebody at OBI?

A. Somebody at OBI.

Q. Who created the various new class of trade descriptions?

A. The company.

Q. Was that something you guided them on or --

A. It was not.

Q. Was that something they created for the litigation or was that something they were using on their own?

A. I don't know the answer to that.

Q. Do you know who at OBI was involved in that process?

A. No. It was one of my staff who worked with one of the attorneys in the company.

Q. Just so I understand this, at some

point in time if we asked internally at OBI, "What COT is San Francisco General Hospital," the answer would have been Paraguard Physicians, right?

MR. SCHAU: Object to form.

A. I don't know the answer to that.

Q. Was the old COT something they were actually using for some purpose at OBI?

A. I don't know.

Q. Okay. Now, the new COT description we're looking at here, is that something Dr. Hartman was given in advance of his report?

A. I don't know when it was produced.

Q. And you don't know why the company went and did this new COT description. Meaning whether or not it was for the litigation or for some other purpose.

A. Correct.

Q. Okay. But there's no question that this is a more accurate -- I'll concede on some of these that the new COT seems to be more accurate than the old COT.

A. Correct.

are in, which customers are out.

Can you quantify for me what the impact was of that, of just the reclassification of classes of trade?

MR. SCHAU: Object to form.

A. How do you define reclassification?

Q. Well, you have a bunch of assumptions here as to which things are in or out and then you also say that, "For Remicade, we excluded certain customers because they weren't in the proper classes, Dr. Hartman shouldn't have included them."

Putting aside the assumptions, let's just talk about the customers that you took out that Dr. Hartman included.

Can you tell me what the impact of that was?

A. Not off the top of my head, nor do I think we did those -- I don't believe we did those calculations.

Q. Okay. Same question for Procrit.

A. Yes, same answer.

Q. Okay. Let's talk about your, I'm going to go down attachment 2, your statement of assumptions.

Number 2, your exclusion of service fees and prompt pay discounts, can you tell me what the impact of excluding that was?

A. We didn't calculate an impact.

Q. Pardon?

A. We did not calculate an impact.

Q. So you don't know what it is.

A. No.

Q. But presumably, the effect was to raise the ASP.

A. Could you repeat the question?

Q. By excluding service fees and prompt pay discounts, you effectively raised the ASP, isn't that right?

A. Yes.

Q. Okay. Same question for number 3, the patient assistance program fees. Do you know what the impact of excluding them was?

A. No, I do not.

Q. And excluding them also had the effect of raising the ASP, right?

A. Yes.

Q. Okay. Same question for transactions with invoices postdating the order. Excluding them had the effect of raising the ASP, right?

A. Correct.

Q. Can you tell me what the impact of that exclusion was?

A. No.

Q. Same questions for units with the sales price of zero. Can you tell me what the impact of excluding them was?

A. No.

Q. But it would have had the effect of raising the ASP.

A. Yes.

Q. Again, for -- well, number 6, do you know what the impact of your weighted average AWP was?

A. No.

Q. So you don't know what effect that

would have had. Would that have had the effect of raising or lowering the spreads?

A. Would depend. Could have been in either direction.

Q. And the same for number 8, the managed care analysis, did you ever figure out what the impact of that was?

A. The impact of what?

Q. Of adding in rebates, of using the managed care rebates for Centocor as a reduction of AWP.

A. The impact of what?

Q. The impact to spread calculations.

A. It would decrease the spread.

Q. It would decrease the sped. But did you ever try to figure out by what percentage or --

A. No.

Q. -- it would?

A. No.

Q. And all the assumptions we're looking at here, assumptions 1 through 8, they were all

made because counsel told you to make them, right?

A. Under the direction of counsel, yes.

MR. HOFFMAN: You want to step out for a second? Why don't you give us thirty seconds to step out.

(Recess taken.)

MR. MACORETTA: All right, Mr. Dukes, let me show you what we're going to mark as Exhibit Dukes 012.

(Deposition Exhibit Dukes 012, MDL-OB100015367, marked for identification, as of this date.)

(Document placed before the witness.)

EXAMINATION (Cont'd.)

BY MR. MACORETTA:

Q. Mr. Dukes, have you ever seen this before?

A. I do not recall ever seeing this schedule.

Q. Do you know what the reference to "gross" and "net" ASP is in this document?

A. I do not.

EXHIBIT 3

UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION	MDL NO. 1456 Civil Action No. 01-12257-PBS
	Hon. Patti B. Saris
THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339	**FILED UNDER SEAL**

DECLARATION OF JAYSON S. DUKES IN SUPPORT OF THE JOHNSON & JOHNSON DEFENDANTS' MOTION FOR SUMMARY JUDGMENT AS TO CLASS 1 AND CLASS 2

CORRECTED

QUALIFICATIONS AND COMPENSATION

1. I am a Managing Director in the Forensic and Litigation Consulting Practice of FTI Consulting, and a part of FTI's Life Sciences Regulatory Practice. FTI Consulting is a multi-disciplinary consulting firm with practices in financial restructuring, forensic and litigation consulting, and economic consulting.

2. I am a Certified Public Accountant and I received a Bachelor's Degree in Accounting from the University of Georgia.

3. I have assisted in resolving disputes across a wide variety of industries for nearly 15 years. I have advised healthcare providers, pharmaceutical companies, and other life sciences clients on financial, accounting, and economic matters. My current clients include Bristol-Myers Squibb, Wyeth, Johnson & Johnson, and HCA.

4. I have particular expertise in the analysis of pharmaceutical pricing practices, including rebating, discounting, and other commonly used financial incentives. My curriculum vitae is annexed to this Declaration as Attachment 1.

5. While I have directed all of the work connected with this engagement, I have been assisted by several other FTI employees.

6. FTI Consulting's fees for this engagement are based upon time expended and expenses incurred. My billing rate is $424 per hour. The rates charged by the other FTI Consulting employees who have assisted me in this engagement range from $195 per hour to $495 per hour.

II. SCOPE OF ASSIGNMENT

7. FTI Consulting was retained by Patterson, Belknap, Webb & Tyler LLP, attorneys for the Johnson & Johnson Defendants, to perform data analyses and financial calculations relating to Procrit®, a product sold by Ortho Biotech Products, L.P., and Remicade®, a product sold by Centocor, Inc.

8. First, FTI Consulting was asked to calculate the average selling price ("ASP") for Procrit® and Remicade®, by product National Drug Code ("NDC"), by year. We were asked to calculate the ASPs using the same two methodologies purportedly used by plaintiffs' expert, Dr. Raymond S. Hartman, as described in his reports dated December 15, 2005 and February 3, 2006.

9. Second, FTI Consulting was asked to calculate ASPs for Procrit® and Remicade® on a weighted average, per unit basis, by year, across all NDCs. Dr. Hartman's reports did not include such calculations.

10. Third, FTI Consulting was asked to calculate the "spreads" between the above-described ASPs, and the published AWPs for Procrit® and Remicade®. The term "spread" is used in this Declaration in the same manner in which it was used in Dr. Hartman's reports, *i.e.*, it is the difference between AWP and ASP, expressed as a

IV. CALCULATIONS OF THE PROCRIT® AND REMICADE® ASPS AND ASSOCIATED "SPREADS" AS PER THE METHODOLOGY DESCRIBED IN DR. HARTMAN'S DECEMBER 15, 2005 REPORT

A. Dr. Hartman's Calculations as per the Methodology Described in Dr. Hartman's December 15, 2005 Report

25. Dr. Hartman's December 15, 2005 calculations of the Procrit® and Remicade® ASPs were attached to his December 15, 2005 Report as Attachment G.4.a. A copy of that Attachment is annexed to this Declaration as Exhibit 3.

26. Dr. Hartman's December 15, 2005 calculations of the Procrit® and Remicade® "spreads" were attached to his December 15, 2005 Report as Attachment G.4.c. A copy of that Attachment is annexed to this Declaration as Exhibit 4.

27. Dr. Hartman's December 15, 2005 calculations of Procrit®'s ASPs, by NDC, and by year, yielded 116 separate "spread" calculations. He identifies 97 Procrit "spreads" that were less than 30% (84%), three Procrit® "spreads" that were equal to 30% (3%), and 16 Procrit® "spreads" that exceeded 30% (14%).[1]

28. Dr. Hartman's December 15, 2005 calculations of Remicade®'s ASPs, by NDC, and by year, yield six "spread" calculations, all of which exceed 30%. He finds that Remicade®'s "spreads" were 30.8% in 1998, 33.4% in 1999, 31.9% in 2000, 36.1% in 2001, 33.9% in 2002, and 34.3% in 2003.

B. FTI Consulting's Calculations as per the Methodology Described in Dr. Hartman's December 15, 2005 Report

29. When my staff and I applied the methodology described in Dr. Hartman's December 15, 2005 Report, excluding the hospital, managed care, and government transactions identified in Exhibit 1, we found that the ASPs for Procrit® are frequently higher than those listed in Attachment G.4.a of Dr. Hartman's Report. Our calculations of Procrit®'s ASPs, by NDC, and by year, are shown in the table annexed to this Declaration as Exhibit 5.

30. When my staff and I applied the methodology described in Dr. Hartman's December 15, 2005 Report, excluding the hospital, managed care, and government transactions identified in Exhibit 1, we found only one Procrit® "spread," for one Procrit® NDC, for one year, that exceeded 30%, and I suspect that that one figure may reflect data anomalies, which I am continuing to investigate. Our calculations of Procrit®'s

[1] In his December 15, 2005 Report, Dr. Hartman's calculated three Procrit® "spreads" that allegedly exceeded 50%, including one NDC in 1993 that was 221.3%. In my opinion, based upon my own calculations, these three "spread" calculations (and others) are incorrect. I note that Dr. Hartman's second set of calculations, discussed below, do not show any NDCs with "spreads" above 50%, and only one NDC with a "spread" above 40%. (The 221.3% "spread" is reduced to 35.3%.) I interpret Dr. Hartman's revisions to suggest that he agrees with me that his initial calculations showing three Procrit® "spreads" in excess of 50% were incorrect.

Attachment 2
Statement of Assumptions

1. Identification of Remicade Direct Sales and Chargeback Data Entry Errors

I have excluded from my ASPs calculations, certain transactions Centocor represents to be data entry errors. A schedule of these transactions is provided at Exhibit 19.

2. Identification of Specialty Distributors Service Fees

We also excluded the effects of service fees and prompt pay discounts earned by specialty distributors and to wholesalers from our Remicade® ASP calculations. A schedule of these transactions is provided at Exhibit 20.

3. Patient Assistance Program Fees

Nova Factor and Priority healthcare were paid fees for their role in administering Centocor's Patient Assistance Program. These fees would appear on a Remicade® invoice as a discount, but they are fees for services, rather than a reduction in the list price. Accordingly, the effects of these discounts were excluded from my ASP calculations. A schedule of these transactions is provided at Exhibit 21.

4. Identification of Transactions with Invoices Postdating the Order

Certain Remicade® sales orders were placed prior to a price increase going into effect. In these instances the related invoices that were issued on or after the effective date of the price increase, reflected the price in effect at time of order. I therefore adjusted my ASP to AWP comparisons to account for these timing differences. A schedule of these transactions is provided at Exhibit 22.

5. Units with a sales price of $0.

Transactions with units where the sales price was $0 were excluded from our ASP calculation for both Procrit® and Remicade®. A listing of excluded transactions is provided at Exhibits 23 and 24.

6. AWPs Employed in Spread Comparison

In instances where a price change occurred during a year, I used a weighted average to calculate a single AWP to be used when calculating the spread for a particular NDC for a year. I weighted the average based upon direct sales unit sold less units with a sales price of $0.

7. Calculating Procrit ASP across all NDCs by Year

For purposes of calculating an ASP for Procrit across all NDCs for a year as well as for comparing this calculated ASP to an equivalent ASP calculation by Dr. Hartman, I needed to employ several assumptions when performing these calculations. First, for my ASP calculations, I needed to calculate a weighted average AWP across all NDCs for a particular year. I used direct sales unit sold

Attachment 2
Statement of Assumptions

less units with a sales price of $0 as the basis for weighting the AWP. Second, I needed to calculate a weighted average for Dr. Hartman's ASP calculations. I used direct sales unit sold less units with a sales price of $0 as the basis for weighting the AWP.

8. Remicade® Managed Care Analysis

For the purpose of recalculating the "spreads" for Remicade treating managed care rebates as a credit against the "spread", I considered the following information. First, I identified that Centocor paid managed care rebates for Remicade® in the amounts of $411,727, $7,334,593 and $25,367,372 for 2001, 2002, and 2003 respectively. Second, I calculated an average managed care rebate paid per unit per year in the amounts of $.30, $3.04 and $8.50 for 2001, 2002 and 2003 respectively. I then calculated a net price paid per unit per year based upon the following equation: AWP per unit – Average Managed Care Rebate Paid Per Unit. I then compared the net price paid to my previously calculated ASP to determine the recalculated "spread". I employed the same methodology for calculating this "spread" as the methodology employed for the "spread" calculation discussed at ¶ 10 of the Declaration.

Exhibit 5

FTI Comparison of ASP Calculations - Dr. Hartman's Declaration Dated December 15, 2005

Excludes Government, Managed Care, and Hospital Sales

Exhibit 5

		1991		1992		1993		1994		1995		1996		1997	
Product	**NDC**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**
Procrit	All NDCs	9.68	9.56	9.58	9.42	9.43	9.36	9.47	9.32	9.18	9.36	8.95	9.26	9.28	9.43
Procrit	00062740003	235.17	234.83	234.63	232.31	238.18	234.76								
Procrit	00062740103	556.83	557.00	555.35	554.09	554.28	553.23								
Procrit	00062740201	115.76	115.77	115.21	115.28	116.53	117.14								
Procrit	00062740501	178.21	178.46	172.27	172.36	176.20	176.94								
Procrit	59676030201					44.81		115.74	116.45	115.49	117.21	115.93	117.22	116.21	117.75
Procrit	59676030202					496.36	497.71	478.79	492.02	463.05	484.50	458.72	473.71		475.01
Procrit	59676030301							173.90	174.11	172.20	175.00	173.89	175.60	174.56	176.52
Procrit	59676030302					729.92	736.71	708.87	726.79	700.23	720.77	687.07	714.84		719.08
Procrit	59676030401					190.56	192.28	232.21	232.54	228.63	234.47	231.20	235.17	232.99	236.54
Procrit	59676030402					952.45	960.16	950.37	963.63	934.40	954.21	923.04	947.11		952.83
Procrit	59676031001					553.90	552.82	553.27	552.39	525.13	556.61	537.43	556.52	556.33	574.35
Procrit	59676031002					2,282.20	2,285.15	2,304.67	2,307.42	2,259.60	2,296.31	2,239.98	2,270.73		2,304.56
Procrit	59676031201							2,280.00	1,140.00	1,085.61	1,128.44	930.85	1,103.09	1,063.35	1,111.53
Procrit	59676032001													1,082.05	1,143.21
Procrit	59676034001														
Remicade	57894003001														

		1998		1999		2000		2001		2002		2003	
Product	**NDC**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**	**Plaintiff**	**FTI**
Procrit	All NDCs	9.27	9.64	9.44	9.63	9.93	10.01	10.12	10.29	10.54	10.62	10.25	10.60
Procrit	00062740003												
Procrit	00062740103												
Procrit	00062740201												
Procrit	00062740501												
Procrit	59676030201	116.16	118.09	116.08	118.22	123.88	123.27	127.52	127.10	133.02	131.19	135.83	132.14
Procrit	59676030202	461.66	480.81	474.87	482.56	516.66	507.97	506.57	515.81	499.83	523.60	491.04	531.80
Procrit	59676030301	175.42	177.20	175.23	177.14	185.22	184.06	190.96	190.57	198.91	196.05	202.95	197.05
Procrit	59676030302	701.15	725.03	716.18	727.50	767.26	753.43	773.21	776.77	768.36	792.24	804.01	803.57
Procrit	59676030401	234.71	237.38	234.33	237.58	246.32	247.22	253.34	256.01	262.65	263.25	265.76	264.32
Procrit	59676030402	942.60	970.84	953.33	969.04	1,040.04	1,006.98	1,044.36	1,036.67	1,088.63	1,072.42	1,090.44	1,078.62
Procrit	59676031001	578.68	590.43	578.90	590.19	612.92	614.50	632.47	637.30	656.85	656.33	657.09	655.43
Procrit	59676031002	2,299.54	2,382.24	2,289.15	2,387.21	2,454.13	2,499.88	2,498.72	2,570.54	2,621.10	2,664.12	2,630.80	2,665.61
Procrit	57894003001	1,123.14	1,150.17	1,131.46	1,159.73	1,218.72	1,217.94	1,237.79	1,248.11	1,288.71	1,289.55	1,275.43	1,284.75
Procrit	59676032001	1,066.06	1,150.28	1,096.11	1,149.04	1,163.83	1,194.86	1,191.89	1,230.43	1,247.37	1,270.94	1,232.54	1,271.71
Procrit	59676034001			1,533.40	1,541.36	1,573.92	1,598.04	1,599.67	1,642.73	1,673.13	1,696.74	1,588.59	1,691.61
Remicade	57894003001	447.26	450.00	458.23	463.98	486.17	495.17	508.25	524.19	516.65	532.01	514.98	532.01

EXHIBIT 4

THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

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IN RE: PHARMACEUTICAL	MDL DOCKET NO.
INDUSTRY AVERAGE WHOLESALE	01CV12257-PBS
PRICE LITIGATION	
**********	MARCH 1, 2006
THIS DOCUMENT RELATES TO:	VOLUME: V
ALL ACTIONS	PAGES: 1169-1469

****

C O N F I D E N T I A L

CONTINUED VIDEOTAPED DEPOSITION OF RAYMOND S. HARTMAN, PH.D., called as a witness by and on behalf of the Defendants, pursuant to the applicable provisions of the Federal Rules of Civil Procedure, before P. Jodi Ohnemus, Notary Public, Certified Shorthand Reporter, Certified Realtime Reporter, and Registered Merit Reporter, within and for the Commonwealth of Massachusetts, at the offices of Dwyer & Collora, LLP, 600 Atlantic Avenue, Boston, Massachusetts, on Wednesday, 1 March, 2006, commencing at 9:46 a.m.

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drugs. And so, the speed limit was an implicit understanding built into the reimbursement formula -- formulae -- of payers and -- of payers.
Q. Are you saying that manufacturers understood that there was a speed limit of 30?
A. I'm saying that manufacturers understood that payers had certain expectations, and the upper bounds -- I'm using an upper bound of what those expectations were. I'm saying that the expectations ranged anywhere from 18 to 26 percent, 27 percent. I'm being conservative to say, okay, let's take 30 percent. But that they understood that and that that was -- that knowing that, and knowing that the -- that the payers were not going to know that they were speeding or that they were -- they were exceeding that, that was the reason that the -- the alleged fraud allowed them to -- to use that inflation to move market share.
Q. If -- if we use your -- stick with your speeding analogy for a moment, would it be fair to characterize it as there was a -- a sign -- this

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implicit sign posted that said 30 miles an hour for private payers, and for government, the speed limit was zero? Is that a fair characterization of your -- of your analysis here in -- in your speeding context?
MR. NALVEN: Objection.
A. A fair -- a fair analysis of my speeding context -- of my speeding context was that there was a relationship between AWP and ASP, the maximum of which I've taken as 30 percent, a conservative upper bound. That was -- that was for all units sold. So that's for government and for nongovernment. That's what the understanding was in the market.
Q. Well, I thought your -- your opinion is that with respect to government it was zero.
A. No, my understanding with respect to government is that if -- in my declaration of December 15th, that if a drug exceeds the speed limit, then there is -- there are statutory -- if they don't exceed the speed limit, then it's not zero. The speed limit is what it is. And it only

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becomes subject to liability if it exceeds the speed limit.
Under the Medicare regulations, as reiterated in my Footnote 13, that indicates the extent to which damages would occur if the speed limit is exceeded. And that's -- that is a -- that's a -- those damages are not the threshold of behavior or liability. That's just a damage calculation, which is a different calculation, which has that zero in it based on my reading of the -- of the CFR.
Q. But in order to be -- in order to be subject to damages for Medicare Part B sales, you have to violate your speed limit of 30, right?
A. In my December 15th declaration, that was the approach, yes.
Q. Okay. And have you altered that view?
A. I have no view of what -- that is a legal view. In my supplemental declaration I was asked to assess what the implication would be for damages and liability if -- if the zero threshold applied for Medicare, but that's not -- that was

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something I was asked to do by counsel, and I have --
Q. So --
A. I have a view as what market expectations were and what everyone in the market understood transactions costs were relative to posted AWPs.
Q. So, if we have your zero -- based on your supplemental report, if you have a zero liability threshold and a 30-percent threshold liability, again, using your speeding analogy, there are two different speed limits posted on the road, right?
A. The -- the speed limit that's posted on the road is the understanding of the relationship of a list price and transactions price. And that's what's posted.
Now, the -- how policemen have enforced that speed limit, what that's -- there's -- it's a different -- the analogy would be in the supplemental I've been asked to assume that even though the -- the speed limit is 30 percent, we